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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,443	07/16/2003	Francesco Visinoni	00366.000183	6949
5514 7590 12/05/2007 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EXAMINER KRASS, FREDERICK F	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 12/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/619,443

Applicant(s)

VISINONI, FRANCESCO

Examiner

Frederick Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

Since a new ground of rejection follows which was not necessitated by applicant's amendment, this action is NON-FINAL.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3, 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Harrison (USP 4,493,821).

The primary reference discloses fixatives comprising water, 20 to 80 percent by weight concentrated (70 to 90%) ethanol, 15 to 70 percent propylene glycol, and an osmotic agent, e.g., a sugar such as glucose.¹ Other additives include salts and acids. See the passage bridging column 2, line 29 to column 3, line 10. The primary reference differs from the instant claims in its silence regarding poly vinyl alcohol.²

The secondary reference discloses fixatives for various uses, including histological applications (column 1, first paragraph), and teaches that for precoated slides it is desirable to add a quantity of a film forming adjuvant such as polyvinyl alcohol to the fixative in an amount ranging from about 10 to 20% by weight in order to enhance adhesion of the fixed specimen. (Column 3, lines 7-15). The secondary reference differs from the instant claims insofar as it does not disclose the use of ethanol.

It would have been obvious to have added about 10 to 20% by weight polyvinyl alcohol to the fixatives of the primary reference when preparing precoated slides therefrom, motivated by the desire to provide the improved adhesion taught by the secondary reference.

¹ One skilled in the art will appreciate that the prior art term "propylene glycol" is equivalent to applicant's recitation of "1,2-propanediol", since it is well known that propylene glycol is provided commercially available as in the form of its 1,2-isomer. See USP 7,084,310.

² The prior art also differs from instant claim 5 insofar as it does not specify the percentage of osmotic agent used. Generally, however, it is *prima facie* obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 205 USPQ 215 (CCPA 1980); and *In re Peterson*, 65 USPQ2d 1379 (Fed. Cir. 2003). Since other useful osmotic agents disclosed include sodium chloride, which would be used in only very small amounts, one would reasonably expect to use sugars in similarly small amounts, e.g. from 0.05 to 2 percent by weight.

2) Claim 4 is rejected under 35 USC 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Harrison (USP 4,493,821), the combination being taken further in view of Bonner (Journal of Solution Chemistry, volume 1, number 5, pages 315-324).

The primary and secondary references, and the rationale for combining their teachings, have been discussed in detail supra. The compositions suggested by their combined teachings differ from those recited instantly insofar as neither reference explicitly suggests the use of a hexitol, e.g., sorbitol. The primary reference does clearly suggest the use of osmotic agents generally, however, in its use of the qualifiers “such as” and “the like” at column 2, lines 54 and 55.

Sorbitol is a known osmotic agent as illustrated by the tertiary reference. It would have been obvious to have used sorbitol as an osmotic agent in the compositions suggested by the combined teachings of the primary reference and secondary references, motivated by the recognition that same is a known osmotic agent as illustrated by the tertiary reference. (This reasoning is entirely consistent with established precedent which holds that generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair & Carroll Co. v. Interchemical Corp., 325 US 327, 65 USPQ 297 (1945). See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960)).

3) Claims 1-3 and 5-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Slifkin (USP 5,508,175).

This rejection is maintained.

Applicant argues (remarks, page 5, third paragraph) that:

It is respectfully submitted that the advantages of the present invention would not have been rendered obvious in view of Siegfried and Slifkin. In Slifkin, polyvinyl alcohol is not used as a fixative in the histological sense, but as an adhesive for temporary or permanent mounting of fresh specimens for parasitology. In the present invention the polyvinyl alcohol when present in combination with the other claim recited components acts to preserve cellular architecture, stabilize the intracellular structure in order to avoid the washing effect of a pure alcohol fixation and preserve the background substance of the tissues. It has also been found that the addition of polyvinyl alcohol to the other components of the present invention results in an overall morphological appearance of the tissue that is quite different than a composition that does not contain polyvinyl alcohol. As noted in the specification, the fixative of the present invention is highly effective for histological purposes, i.e., the study of cell structure, and cytological purpose, i.e. study of the formation, structure and function of cells. See specification at page 4, lines 17-20.

These arguments are not persuasive.

In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. See MPEP 2141.01(a) [R-3]. In this case, both references are from the field of fixation. Moreover, the secondary reference teaches that "PVA is a particularly useful mounting medium [because] it causes no distortion under microscopy" at column 2, lines 56-60. Since the primary reference discloses the production of microscopy mounts (see column 4, lines 35-39), lack of distortion would also be advantageous there. Accordingly, on both counts, the references are viewed as "analagous art", and thus fairly combinable.

Regarding applicant's allegations of unexpected results ("different" overall morphological appearance), no factual evidence is seen to support same. Mere conclusory statements in an applicant's specification, unsupported by objective evidence, are generally given little weight in determining patentability. See In re Greenfield, 197 USPQ 227, 229 (C.C.P.A. 1978).

4) Claim 4 is rejected under 35 USC 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Slifkin (USP 5,508,175), the combination being taken further in view of Bonner (Journal of Solution Chemistry, volume 1, number 5, pages 315-324).

The primary and secondary references, and the rationale for combining their teachings, have been discussed in detail in the previous Office action, the text of which is incorporated by reference herein. The compositions suggested by their combined teachings differ from those recited instantly insofar as neither reference explicitly suggests the use of a hexitol, e.g., sorbitol. The primary reference does clearly suggest the use of osmotic agents generally, however, in its use of the qualifiers "such as" and "the like" at column 2, lines 54 and 55.

Sorbitol is a known osmotic agent as illustrated by the tertiary reference. It would have been obvious to have used sorbitol as an osmotic agent in the compositions suggested by the combined teachings of the primary and secondary references, motivated by the recognition that same is a known osmotic agent as illustrated by the tertiary reference. (This reasoning is entirely consistent with established precedent which holds that generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair & Carroll Co. v. Interchemical Corp., 325 US 327, 65 USPQ 297 (1945). See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960)).

Correspondence

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

